

REMARKS

Claims 1, 4 - 10 and 15 - 23 are pending in the application. Claim 1 is currently amended. Claims 4 -10 are original, claims 15 - 23 were previously presented as new claims added in a preliminary amendment. A copy of the claims now pending in the application in accord with 37 CFR 1.121, as revised, has been provided.

No new matter has been introduced by virtue of the amendments made herein. Accordingly, applicants respectfully request their entry. In view of the amendments made herein and the remarks below, applicants respectfully request reconsideration and withdrawal of the rejection set forth in the May 21, 2004 office action.

Specification

The Examiner required correction of the paragraph that was added at page 7, after line 14. The Examiner objected to the phrase "R⁵ and R⁶ are as defined in claim 2". Without prejudice and in the interests of facilitating prosecution applicants have amended this paragraph to recite "R⁵ and R⁶ are defined as in formula I above" and respectfully request the Examiner to withdraw the objection.

Rejection under 35 USC § 112, first paragraph

The Examiner rejected claims 15 and 16 under 35 USC § 112, first paragraph as failing to comply with the written description requirement. The Examiner asserts that the species "2-fluoro-N-(4-hydroxy)[sic]-10-aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-trien-5-yl)-benzamide" in claim 15 and 4,5-bistrifluoromethyl-10-aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-triene in claim 16 are not described in the specification.

Applicant submits that 2-fluoro-N-(4-hydroxy-10-aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-trien-5-yl)-benzamide the compound recited in claim 15 may be found in the specification in the "Summary of The Invention" section as the third species in the list of "Examples of specific compounds of the formula I"....

Applicant further submits that 4,5-bistrifluoromethyl-10-aza-tricyclo[6.3.1.0^{2,7}]dodeca-2(7),3,5-triene recited in claim 16 may be found in the specification in the "Summary of The Invention" section as the last species in the list of "Other embodiments compounds of the invention include...."

Applicants submit that claims 15 and 16 are patentable under 35 USC § 112, first paragraph and respectfully request the Examiner to withdraw the rejection.

Rejection under 35 USC § 112, second paragraph

The Examiner rejected claims 1, 7-10 and 15-23 under 35 USC § 112, second paragraph for indefiniteness. The Examiner cited:

a) The recitation of the phrase "...aryl and heteroaryl groups may optionally be substituted with one or more substituents, preferably from zero to two substituents,...." as rendering the claim indefinite. Without prejudice and in the interests of facilitating prosecution applicants have amended claim 1 by deletion of the phrase "preferably from zero to two substituents".

b) Claim 7 as a substantial duplicate of claim 9. Applicants submit that the recitation in claim 7 of "an amount of a compound according to claim 1 that is effective in reducing nicotine addiction or aiding in the cessation or lessening of tobacco use" refers to a specific pharmaceutical composition requiring a specific quantity of a compound according to claim 1 to produce a specific result. Claim 9 differs substantially from claim 7 because it recites a general pharmaceutical composition and does not specify that the quantity of a compound according to claim 1 present in the composition be effective in producing a specific result. Applicants submit that claim 7 which recites a specific pharmaceutical composition is distinct from claim 9 which recites a general pharmaceutical composition and is not a substantial duplicate thereof.

c) Insufficient antecedent basis for the recitation of "and pharmaceutically acceptable salts thereof" in claims 15-23. Without prejudice and in the interests of facilitating prosecution applicants have amended claim 1 to recite the phrase "and pharmaceutically acceptable salts thereof" which was inadvertently omitted from the preliminary amendment to claim 1. Support for this phrase is found throughout the specification, specifically in the "Summary of the Invention" section. Applicants submit that as a result of the foregoing amendment the use of this phrase in claims 15-23 has sufficient antecedent basis.

Without prejudice and in the interests of clarity and of facilitating prosecution applicants have also amended claim 1 by deletion of the word "the" and addition of a comma after the word "hydrogen" in the proviso at the end of the claim.

Applicants submit that currently amended claim 1, claims 7-10 and 15-23 are patentable under 35 USC § 112, second paragraph, and respectfully request the Examiner to withdraw the rejection.

Double Patenting

The Examiner provisionally rejected claims 7-10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/348,381. The Examiner concedes "... the conflicting claims are not identical..." but states "...they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are

embraced by the compositions and method of use of the compounds of the formula where R¹ is hydrogen or ethanone, and R² and/or R³ are methyl, fluoro, trifluoromethyl, nitro, chloro, cyano, hydroxyl, etc.”

Applicants submit that instant claims 7-10 are specifically directed to pharmaceutical compositions and methods of treating conditions and disorders with “...an amount of a compound according to claim 1...” while claims 1-34 of copending Application No. 10/348,381 recite pharmaceutical compositions and methods of use based on a combination of “a nicotine receptor partial agonist or pharmaceutically acceptable salt thereof” and “*an analgesic agent or pharmaceutically acceptable salt thereof*”. Applicants submit that the pharmaceutical compositions and methods of use of instant claims 7 - 10 are patentably distinct from those of claims 1-34 of copending Application No. 10/348,381 under the judicially created doctrine of obviousness-type double patenting and respectfully request the Examiner to withdraw the provisional rejection.

Claims 7-10 were also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/348,399. The Examiner concedes “... the conflicting claims are not identical...” but states “...they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of the formula where R¹ is hydrogen or ethanone, and R² and/or R³ are methyl, fluoro, trifluoromethyl, nitro, chloro, cyano, hydroxyl, etc.”

Applicants submit that instant claims 7-10 are specifically directed to pharmaceutical compositions and methods of treating conditions and disorders with “...an amount of a compound according to claim 1...” while claims 1-18 of copending Application No. 10/348,399 recite pharmaceutical compositions and methods of use based on a combination of “a nicotine receptor partial agonist *and an anti-depressant or anxiolytic agent*” and claims 19-21 of Application No. 10/348,399 are directed to “A method for treating a mammal *having a condition which presents with* tobacco or nicotine addiction, nicotine withdrawal symptoms, alcohol dependence or cocaine or other substance, addictions....”. Applicants submit that the pharmaceutical compositions and methods of use of instant claims 7-10 are patentably distinct from those of claims 1-21 of copending Application No. 10/348,399 under the judicially created doctrine of obviousness-type double patenting and respectfully request the Examiner to withdraw the provisional rejection.

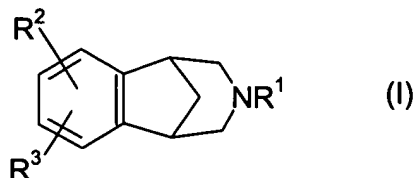
The Examiner also provisionally rejected claims 7-10 were under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-6, 8, 10 and 15-26 of copending Application No. 10/075,348. The Examiner concedes “... the conflicting claims are not identical...” but states “...they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are

embraced by the compositions and method of use of the compounds of formula (I) where R^1 is hydrogen, (C_1-C_6) alkyl, unconjugated (C_3-C_6) alkenyl, $XC(=O)R^{13}$, benzyl or $-CH_2CH_2-O-(C_1-C_4)$ alkyl, and R^2 and R^3 are hydrogen, (C_2-C_6) alkenyl, (C_2-C_6) alkynyl, hydroxyl, nitro, amino, halo, cyano, etc.”

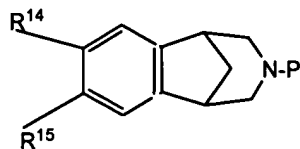
Applicants submit that instant claims 7-10 are specifically directed to pharmaceutical compositions and methods of treating conditions and disorders with “...an amount of a compound according to claim 1...” while currently pending claims 1, 3-6, 8, 10 and 15-26 of copending Application No. 10/075,348 recite pharmaceutical compositions and methods of use based on a combination of a compound of the formula (I) “...and a compound that is selected from an antidepressant, a muscarinic agonist, a neurotrophic factors, an agent that slows or arrests Alzheimer’s disease, an amyloid aggregation inhibitor, a secretase inhibitor, a tau kinase inhibitor, neuronal antiinflammatory agent and estrogen-like therapeutic agent.” Applicants submit that the pharmaceutical compositions and methods of use of instant claims 7- 10 are patentably distinct from those of currently pending claims 1, 3-6, 8, 10 and 15-26 of copending Application No. 10/075,348 under the judicially created doctrine of obviousness-type double patenting and respectfully request the Examiner to withdraw the provisional rejection.

In addition, claim 1 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/127,267. The Examiner concedes “... the conflicting claims are not identical...” but states “...they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of the formula where instant R^1 is hydrogen, methyl, $-C(=O)H$, or $-C(=O)(C_1-C_6)$ alkyl, benzyl or trifluoroacetyl, and R^2 and R^3 are each amino.”

Applicants submit that instant claim 1 recites a compound of formula (I)



wherein, contrary to the Examiner’s assertion, the definition of R^1 does not encompass $-C(=O)H$, or $-C(=O)(C_1-C_6)$ alkyl, or trifluoroacetyl, and current claim 11 of copending Application No. 10/127,267 recites a compound of the following formula:



wherein R^{14} and R^{15} are each amino. However, without prejudice and in the interests of facilitating prosecution, and without conceding the correctness of the Examiner’s position, the

applicants have amended instant claim 1 to recite the proviso "... (d) when both R² and R³ are amino and meta to a fused ring carbon atom then R¹ cannot be hydrogen, methyl or benzyl..." Applicants submit that currently amended claim 1 is patentably distinct from those of currently pending claims 11 of copending Application No. 10/127,267 under the judicially created doctrine of obviousness-type double patenting and respectfully request the Examiner to withdraw the provisional rejection.

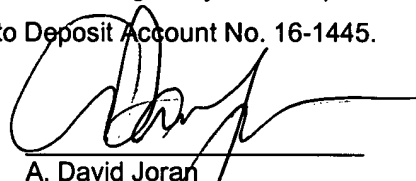
Claim Objections

The Examiner objected to claims 4-6 under 37 CFR 1.75(c) as being in improper form, "because a multiple dependent claim should refer to other claims in the alternative only." Applicants submit the Examiner errs as claims 4-6 depend only on claim 1 and are in proper form. Applicants respectfully request that the Examiner withdraw the objections to claims 4-6.

In view of the amendments set forth herein and remarks above, the applicants respectfully submit that the pending claims are fully allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

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